

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1, 5, 6, 9, 13, 15, 18, 20-25, and 38 are pending in the instant application. Claim 38 is new and is drawn to applicant's elected species.

### ***Information Disclosure Statement***

The information disclosure statement filed on 12/1/2009 has been considered by the examiner.

### ***Previous Objections/Rejections***

*Any rejections or objections stated of record in the office action mailed on 12/1/2009 that are not explicitly addressed herein below, are hereby withdrawn in light of applicant's arguments and/or amendments filed 4/1/2010.*

### **35 USC § 112 (2<sup>nd</sup> Paragraph)**

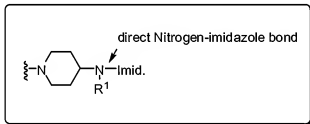
**The 112 2<sup>nd</sup> rejection of claims 1, 5, 6, 9, 13, 15, 18, and 21-25 is maintained.**

Applicant's arguments, see Remarks, filed 4/1/2010, with respect to the rejection set forth in the Non-Final Office Action mailed 12/1/2009, have been fully considered but are not found persuasive.

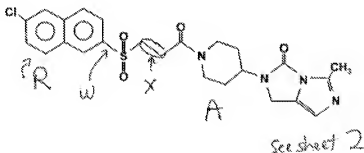
Applicant's arguments are based on the following statements:

"When a substituent of the imidazole ring B does not form a ring together with R<sup>1</sup> of Z<sup>2</sup>, where Z<sup>2</sup> is -N(R<sup>1</sup>) -, the nitrogen atom of Z<sup>2</sup> is bound to the ring B and forms "Ring A-N(R<sup>1</sup>) - Ring B". Thus, the three groups to which the three covalent bonds of the nitrogen atom are bound are defined."

The examiner partially agrees with this statement but the claims are still rendered indefinite based on how  $-N(R^1)-$  is defined in claim 1. Claim 1 explicitly reads that  $Z^2$  is  $-N(R^1)-$ . This could imply that substituent  $R^1$  is bonded to ring "B" in formula I, while the nitrogen atom is only bonded to said  $R^1$  and the piperidine ring giving rise to a divalent nitrogen. On the other hand, this could imply that the nitrogen atom is bonded directly to the piperidine ring, ring "B", and  $R^1$  (see below and in ex parte Quayle mailed 4/1/2009):



To further support the examiner's position regarding the ambiguity, applicant's elected specie has the following structure and does not fall within the scope of the latter scenario (wherein the nitrogen atom is bonded directly to the piperidine ring, ring "B", and  $R^1$ ):



Claim 1 reads "that a substituent on the optionally substituted imidazole ring may be taken together with R<sup>1</sup> to form a ring". In the structure above, applicant suggests that R<sup>1</sup> is -CO-. Thus, the substituent on the imidazole ring must be a "methylene group" and is forming a bond with nitrogen to form a ring. In the above situation, the nitrogen is not directly attached to ring "B".

Therefore, based on the claims as written, the metes and bounds of the claims are not clear. Currently, the examiner assumes that claim 1 is directed to indefinite compounds wherein the nitrogen atom of -N(R<sup>1</sup>)- is attached to the piperidine ring and linked to ring "B" via substituent R<sup>1</sup>.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The aforementioned claims recite compositions wherein "the compound is in an amount providing an anticoagulant effect", "the compound is in an amount effective for preventing or treating myocardial infarction, cerebral infarction, etc." What specific amounts of the claimed compounds do applicant's intend to produce the desired effects

for treating the claimed conditions? Thus, the metes and bounds of the claims can not be interpreted and are considered indefinite.

### ***Conclusion***

Claims 1, 5, 6, 9, 13, 15, 18, and 21-25 are rejected. Claims 20 and 38 are allowable. The instantly claimed species are novel with respect to wherein ring "B" forms a bicyclic ring with -N(R<sup>1</sup>)-. The compounds are not taught or fairly suggested by the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

**Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.**

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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